

Remarks

Claims 1 to 3 and 6 to 15 are pending and before the Examiner.

The Examiner rejected claims 1 to 3 and 6 to 12 as allegedly obvious under 35 U.S.C. § 103(a) over Gaviraghi (WO 00/27397) in view of Doi *et al.* (U.S. Patent Publication No. 2004/0058914) and as evidenced by Frisbee *et al.* (WO 99/17744). The Examiner also rejected claims 1 to 3, 6 to 9, and 13 as allegedly obvious under 35 U.S.C. § 103(a) over McGill *et al.* (Clinical Therapeutics 2001) in view of Raghunathan (U.S. Patent No. 4,522,818) as well as Gaviraghi in view of Doi *et al.* and as evidenced by Frisbee *et al.* In addition, the Examiner rejected claims 1 and 14 as allegedly obvious under 35 U.S.C. § 103(a) over Gaviraghi in view of Doi *et al.* and as evidenced by Frisbee *et al.* and further in view of Curatollo *et al.* (U.S. Patent No. 6,068,859), Schnieder (U.S. Patent No. 6,358,986), and as evidenced by Gennaro (*Remington Pharmaceutical Sciences*, 19th ed. 1995, p. 1625). In addition, the Examiner rejected claims 1 and 15 as allegedly obvious under 35 U.S.C. § 103(a) over Gaviraghi in view of Doi *et al.* and as evidenced by Frisbee *et al.* and further in view of Schnieder.

Applicants respectfully traverse each of the obviousness rejections and maintain that they are improper. The instant claims are limited to specific formulation of telmisartan. The specific solution to the formulation problems of telmisartan to provide telmisartan formulations of high solubility (see specification, pages 1 to 3) in the instant application is not disclosed nor suggested in the cited prior art and it therefore cannot be obvious over such art. In particular, Doi *et al.*, Frisbee *et al.*, Raghunathan, and Curatollo *et al.* do not mention or even relate to telmisartan at all and it is unclear why one of skill in the art without knowledge of the instant claimed invention would consult such prior art at all, much less rely on it with the confidence that such teachings could somehow be applied to telmisartan formulations with success, which would be required for one of skill in the art to attempt such a formulation. The present application specifically acknowledges that poloxamers or pluronics and other pharmaceutical excipients were known and even commercially available at the time of filing, but that fact does not make the use each and every excipient known and commercially available in every combination, with every active ingredient, at any amount obvious. There is no reason given why the telmisartan formulation of Gaviraghi would be modified or should be modified, much less how the telmisartan formulation of Gaviraghi should be modified to obtain the

instant claimed invention. In short, none of the cited references provides a motivation or expectation of success in making the instant claimed invention because they do not provide any suggestion that their teachings could be successfully extrapolated to the specific formulation of the instant claimed invention. Since all of the rejections depend on this point, they should all be withdrawn. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejections.

Applicants submit that all the pending claims are allowable and respectfully solicit a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Respectfully submitted,

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